The MALIS* Bipolar Electrosurgical System CMC™ -III

(Catalog No. 80-1170)

Instruction Manual

IMPORTANT:
Please read entire
Instruction Manual before attempting
to operate this unit

Codman
CODMAN & SHURTLEFF, INC.
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SN 061291

*Trademark of Leonard I. Malis, M.D.

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SN 061292

Background
by Leonard Malis, M.D.

The original monopolar and the MALIS Bipolar Coagulators used spark-gap generators to produce their coagulating waveform. The aperiodic waveform and random spike components of the spark-generated waveform produced good coagulation. However, the initial spike of each damped train is always much higher in voltage than the rest of the train, as a requirement for striking the arc in the internal spark gap of the generator. This high voltage initial spike is responsible for the undesirable sparking at the forceps tips and interference with television and monitoring equipment.

Previous electronic tube or solid state coagulators generally provided either damped trains of sine or square waves, or simply repetitive pulses. The synchronizing of these pulses or waves increased undesirable cutting or perforation of vessels being coagulated, as a result of molecular resonance. For this reason, the original MALIS Bipolar Coagulator and its present day version, the MALIS Bipolar Coagulator CMC-I (catalog no. 80-1114) continue to be the choice of most microsurgeons.

The MALIS Bipolar Coagulator and Bipolar Cutter System CMC-II simulated the aperiodic waveform of the spark gap systems, but the leading spike has now been reduced and is proportional to the remainder of the damped asynchronous train. The aperiodic waveform results in the elimination of molecular resonance while control of the first spike of each train results in marked reduction of sparking of the forceps and interference with other equipment. In addition, the waveform parameters are specifically programmed for smoother coagulation, and reduced neuromuscular stimulation, charring, sticking, and vascular perforation.

Bipolar coagulation has been part of microsurgical technique from the very beginning. The old standard unipolar machines worked from a single active electrode to a return plate through a large ground plate or dispersive electrode. A considerable total current, distributed roughly in a geometric cone from the active electrode to the ground plate, had its highest power per tissue volume at the active electrode, but a fair amount of current was distributed in adjacent tissues. The most conductive path to the ground had the highest current density. This could be through the blood in the small vessel being coagulated, thereby inadvertently coagulating the parent vessel. Use of the unipolar coagulator under saline irrigation was not feasible, as the saline, rather than the desired tissue, was th conductive path to ground.

In bipolar coagulation the electrical difference is only in the isolated output and in the lower power requirements. The output of the bipolar generator should be isolated from ground as much as possible, so all current flow takes place between the two tips of the separated forceps. There should be virtually no current flow from either side of the forceps to ground. The current geometry will now be dependent upon the tip size and the angle at which the tips meet, as well as the medium in which they are immersed. If the forceps blades are virtually parallel, and the forceps are deep in saline, there will be major shunting in the saline. If the forceps are bowed or angled so the tips almost m et while the blades are still well separated, the current flow will be mainly between the tips with little shunting. The lowest possible generator output impedance provides the best maintenance of power at the forceps tips with the least decrease in coagulation due to shunting.

The MALIS Bipolar Coagulator and Bipolar Cutter System CMC-II provided a stiffly regulated isolated output with the impedance in the 5 to 10 ohm range. By contrast, output impedance of previously available solid state systems is approximately 150 to 500 ohms. Even the spark-gap MALIS Bipolar Coagulator CMC-I has an output impedance of 40 to 50 ohms. The lower impedance output of the MALIS CMC-II facilitated its use under the constant irrigation desirable for cooling and protecting adjacent delicate structures. Cutting with the CMC-II, using sharp forceps or bipolar loop forceps, was particularly effective for the precise coring of nervous system tumors with minimal bleeding, as compared to other techniques. It was less effective for cutting fibrous tissues or opening skin or fascia.

The MALIS CMC-III Electrosurgical System now provides the higher energy output needed for rapid cutting of all tissues, including dense fibrous layers, shifting the low impedance of the micro cutting automatically to match the power requirements of the high power cut settings. At the same time, the CMC-III continues all of the other advantages already noted for the CMC-II and provides a still lower output impedance for even more effective control of coagulation. A number of other modifications which will make its use easier have also been provided and are described in this manual.

Product Description

The MALIS Bipolar Electrosurgical System CMC-III (catalog no. 80-1170) includes the Generator; a wireless Remote Control for changing power settings as well as operating the cutting and coagulation functions; a Bipedal Pneumatic Footpedal for operating the cutting and coagulation functions; and a Connecting Cable to allow the use of a MALIS Irrigator with the CMC-III. The generator is equipped with a voice synthesizer that provides an audible indication of changes to the power settings. At the surgeon's option, it also announces the operating mode and power setting each time cutting or coagulation is performed. With the exception of the generator, all the above system components may also be ordered separately (see Accessories later in this manual).

MALIS Bipolar Cutting Forceps and standard insulated and non-insulated forceps are available separately, as are reusable and disposable Bipolar Cords. The System may be used with the MALIS Irrigation Module (catalog no. 80-1164). The CODMAN** Floorstand for MALIS CMC-II/III is designed to accommodate the CMC-III Generator and the Irrigator together. (Please see Accessories for ordering information.)

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Warnings and Cautions

Warnings

Read entire instruction manual before attempting to operate this unit.

The MALIS CMC-III is manufactured to cut or coagulate living tissue and should only be used in the medical facility under the supervision of a physician.

Do not attempt to bypass the grounding prong on the generator by using a three-prong to two-prong adaptor. The generator must be properly grounded to ensure operator and patient safety. Grounding reliability can be achieved only when connected to a receptacle marked "Hospital Only" or "Hospital Grade."

Always replace the system's fuse with the appropriate type and value fuse (see Technical Specifications).

Explosion hazard: do not use in the presence of flammable materials; i.e., anesthetics, solvents, cleaning agents, and endogenous gases.

Electrical shock hazard: do not remove cover or back. No user-serviceable components. Send to qualified service personnel for servicing.

Do not apply the output of this generator directly to the heart.

Do not operate the generator near patient devices, such as pacemakers, etc., that are sensitive to radio frequency interference.

The unit should not be modified in any way by any user. Unauthorized modifications to the unit may cause it to malfunction or fail in use.

Before turning on the generator, verify that the supply voltage selector on the power receptacle is set to the correct voltage for the electrical outlet.

Be certain the voice mute switch on the rear panel is in the desired position before actual use begins.

Never adjust the power setting while using the Cut or Coag controls on either the remote control or the footpedal.

When using the remote control to cut or coagulate, pause for at least two seconds before your next selection to allow the power output cycle to complete.

Certain wireless remote controls for other devices may affect the operation of the CMC-III. Exercise caution when using such devices in the vicinity.

Never immerse the MALIS CMC-III generator or remote control in any liquid.

Cautions

Do not operate the MALIS CMC-III at temperatures below 50°F (10°C). Allow the MALIS CMC-III to warm up to at least 50°F before attempting to operate the coagulator.

Keep the generator away from other electrosurgical devices and their cables. Devices producing excessive RF current radiation may cause this unit to produce voice annunciation and to output power.

Patient monitoring electrodes may be used in any biologically suitable location. Needle electrodes offer no hazard with this unit and may also be placed in any location other than in direct contact with the bipolar forceps tips.

Always check that the power cord, remote control, bipolar cord, and footpedal are functioning properly before using in a surgical procedure. Replace if necessary.

It is recommended that insulated bipolar forceps be used when higher power settings are employed.

Cutting with the bipolar forceps can only take place between the tips of the forceps and is limited to tissu and vessels which can be placed between the tips. If the tips of the bipolar forceps come in contact with each other, or if the tips become coated with coagulum, no cutting or coagulating will take place.

Continuous power output, by either footpedal or remote control, must be limited to 40 seconds, with a 20-second rest period.

Controls, Indicators, and Connections

Generator Controls (Figures 1 and 2)

A. Power Switch
Controls the power supplied to the coagulator.

B. Cutting Power Control Switch
Used to increase or decrease the power settings for cutting. (Cutting power control buttons are also located on the remote control set.)

C. Coagulation Power Control Switch
Increases and decreases the power settings for coagulation. (Coagulation power control buttons are also found on the remote control set.)

D. Tone Volume Control
Used to control the volume of the tones which indicate cutting or coagulation power is being delivered to forceps. You can change the tone volume at any time during the operation of the CMC-III, except while cutting or coagulating. While you are using these controls, the tone volume settings will appear in the Microcut Power Display Window (Item V in Figure 5). Afterwards, the display window will again show the actual microcut power setting.

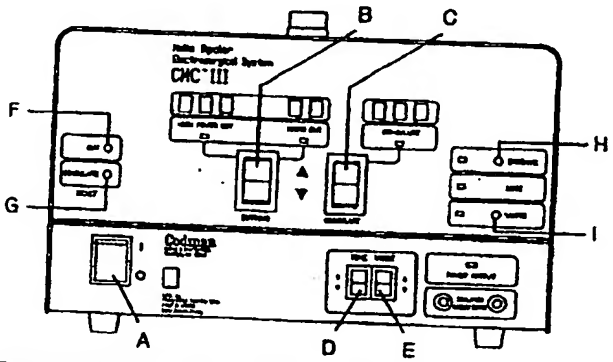


Figure 1. Front Panel Controls (Items A through I)

E. Voice Volume Control
Used to increase or decrease the volume of the voice synthesizer which announces the operating mode being employed and changes in the power settings. You can increase or decrease the voice volume at any time while using the CMC-III, except during cutting or coagulating.

While you are using these controls, the voice volume settings will appear in the Microcut Power Display Window (Item V in Figure 5). Afterwards, the display window will again show the actual microcut power setting.

F. Cutting Reset Button
By pushing this button, you can immediately reset the cutting power to 35 Malis units (or 9 watts).

G. Coaguation Reset Button
You can quickly reset the coagulation power to 35 Malis units (or 9 watts) by pushing this button.

H. Irrigation Mode Button
When the MALIS Irrigator is properly set up and connected to the CMC-III, push this button to disable and enable irrigation. An additional irrigator button is located on the remote control set. The Irrigation Mode Indicator (Figure 5, Item AA) located on the generator will illuminate when the irrigator is enabled, regardless of which of the two switches is used.

I. Watts Display Buttom
Press this button to display the power settings in watts. The Watts Display Indicator (Figure 5, Item CC) will illuminate whenever the power settings are shown in watts.

J. Voice Mute Button
Used to prevent the voice synthesizer from announcing the operating mode being employed and the power settings each time cutting or coagulating is performed. When the voice is muted, the Mute Indicator, Item BB in Figure 5, will illuminate.

K. LED Test Button
When you press this button, all numeric LED's should illuminate as a self-diagnostic test. Any numeric LED which does not illuminate signals a problem requiring attention.

L. Supply Voltage Selector
Use this control to set the generator to the same voltage as the power receptacle you are using.

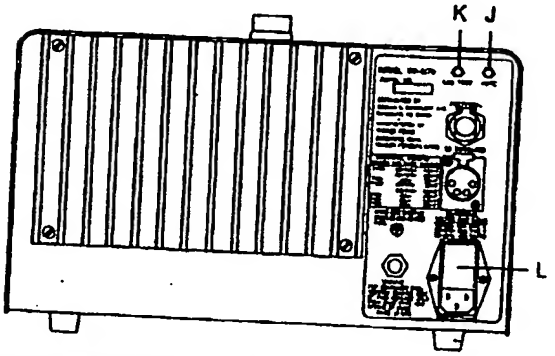


Figure 2. Back Panel Controls (Items J through L)

Remote Control Set Controls (Figure 3)

M. Cutting Output Button
When you press this button, cutting power is delivered to the forceps. (The Cut pedal on the footpedal, Item R in Figure 4, also controls this function.)

N. Coagulation Output Button
By pressing this button, you will cause coagulation power to be delivered to the forceps. (The Coag pedal on the footpedal, Item S in Figure 4, also controls this function.)

O. Coagulation Power Control Button
Use this button to increase or decrease the power setting for coagulation. (The Coag Power Control Switch on the generator, Item C in Figure 1, controls the same function.)

P. Cutting Power Control Button
Increase or decrease the power setting for cutting by means of this button. (The Cutting Power Control Switch on the generator, Item B in Figure 1, controls the same function.)

Q. Irrigation Mode Button
When the MALIS Irrigator is properly set up and connected to the CMC-III, push this button to disable and enable irrigation. An additional irrigator button is located on the generator. The Irrigation Mode Indicator (Figure 5, Item AA) located on the generator will illuminate when the irrigator is enabled, regardless of which of the two switches is used.

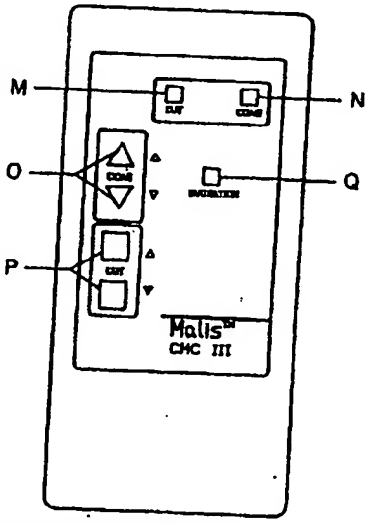


Figure 3. Remote Control (Items M through Q)

Footpedal Controls (Figure 4)

R. Cutting Output Pedal
When you depress this pedal, cutting power is delivered to the forceps. (The Cut button on the remote control, Item M as shown in Figure 3, also controls this function.)

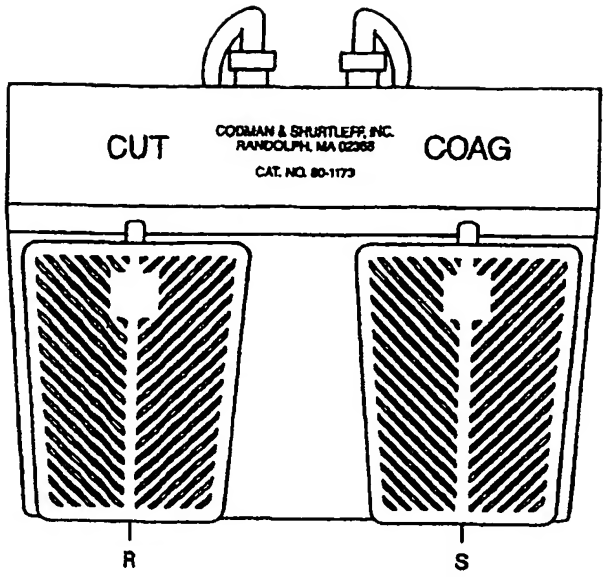


Figure 4. Footpedal Controls (Items R & S)

S. Coagulation Output Pedal
Coagulation power is delivered to the forceps when you depress this pedal. (The Coag button on the remote control, Item N as shown in Figure 3, also controls this function.)

Indicators (Figure 5)

T. Power Output LED
This green LED illuminates whenever power of any kind, for either cutting or coagulation, is delivered to the forceps.

U-W. Power Display Windows
These three sets of windows show the power selections for high power cutting (Item U), microcutting (Item V), and coagulation (Item W). The power selections can be shown in either MALIS Units, or watts; use the Watts Display Button (Item I in Figure 1) to make your choice. When the generator is initially turned on, the setting "35" will appear in both the microcutting and coagulation windows. The high power cutting window will be blank. The following power settings are available for each operating mode.

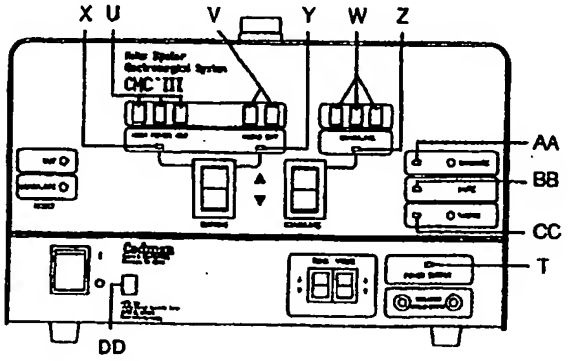


Figure 5. Front Panel Indicators (Items T through DD)

POWER SETTINGS

COAGULATE		MICROCUTTING		HIGH POWER CUTTING	
Malis Units	Watts	Malis Units	Watts	Mali Units	Watts
8	0.7	8	0.7	60	20.0
10	1.0	10	1.0	70	40.0
15	1.6	15	1.6	80	60.0
20	3.0	20	3.0	90	80.0
25	5.0	25	5.0	100	100.0
30	7.0	30	7.0	110	120.0
35	9.0	35	9.0	120	140.0
40	11.0	40	11.0	130	160.0
45	14.0	45	14.0	140	180.0
50	17.0	50	17.0	150	200.0
60	19.0				
70	22.0				
80	24.0				
90	25.0				
100	29.0				
110	32.0				
120	35.0				
130	40.0				
140	45.0				
150	50.0				

X. High Power Cutting LED
This yellow LED will illuminate whenever cutting power in the high range (60 to 150 MALIS units, or 20 to 200 watts) is delivered to the forceps.

Y. Microcutting Power LED
This yellow LED illuminates when cutting power in the micro range (8 to 50 MALIS units, or 0.7 to 17 watts) is delivered to the forceps.

Z. Coagulation Power Light
This blue light will illuminate whenever coagulation power is delivered to the forceps.

AA. Irrigation Mode LED
Irrigation is enabled when this green light is on and a MALIS Irrigator is properly connected. NOTE: To avoid unintentional irrigation, be sure the power on the Irrigator is switched off whenever the CMC-III generator is switched off.

BB. Mute LED
When you disable the voice synthesizer by using the voice mute button (Item J in Figure 2), this green LED will light up.

CC. Watts Display Indicator
If you choose watts to be displayed in the power indicator windows (Items U, V, and W, this Figure) by pressing the watts display button (Item I, Figure 1), this green LED will illuminate.

DD. Infrared Signal Receiver Window
This window receives signals from the remote control set. Do not obscure the window during use.

Tone Indicators (not shown)
The CMC-III generator will produce a tone whenever power is delivered to the forceps. Two different tones are employed to differentiate between coagulation and cutting. A low frequency major chord indicates coagulation.

A higher frequency minor chord indicates cutting. You can control the volume of the tone indicator with the tone volume control (Item D in Figure 1).

Voice Indicator (not shown)
The voice indicator enables you to check or adjust the power setting and mode of operation without removing your eyes from the surgical site. As you change the power setting, the voice indicator announces each new setting. When you use the Cut switch (on either the remote control set or the footpedal) the voice announces either "Microcut" or "Cutting." It also announces the power setting before the generator delivers either cutting or coagulating power to the forceps. You can use the voice volume control (Item E in Figure 1) to change the volume of the voice.

In addition, the voice indicator functions as part of the self-diagnostic feature for the five conditions shown below.

"Internal fuse"	Indicates an internal fuse must be replaced
"Memory error"	Operating malfunction
"Error"	Indicates the two front panel power setting controls were pressed simultaneously
"Footpedal error"	Indicates that both footpedals were pressed simultaneously
"Internal power error"	Operating malfunction

Please refer to the Troubleshooting Guide for further information.

Connections (Figures 6 and 7)

EE. Isolated Bipolar Output Jacks
These jacks accept the banana-type plugs of either the reusable or disposable bipolar cords.

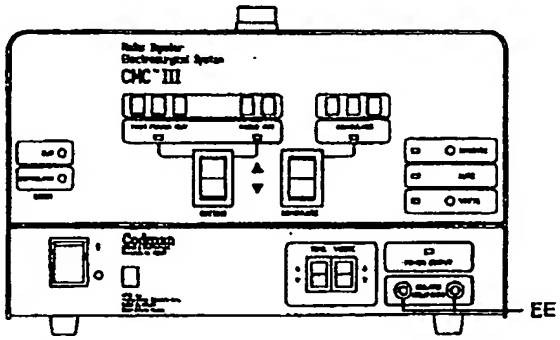


Figure 6. **Front Panel Connections** (Item EE)

FF. Footpedal Receptacle
Accepts the connector of the footpedal.

GG. Irrigator Receptable
You may plug the CMC-III/Irrigator Connecting Cable (catalog no. 80-1174) into the generator here to use the MALIS Irrigation Module (catalog no. 80-1164) along with the CMC-III. Refer to set up instructions in the manual supplied with the connecting cable for more information.

NOTE: To avoid unintentional irrigation, be sure the power on the Irrigation Module is switched to the OFF position whenever the power switch on the CMC-III generator is in the OFF position.

HH. Power Receptacle
This receptacle accepts the three-prong power cord plug and also contains the supply voltage selector and the external fuses. (See Technical Specifications.)

II. Equipotential Connector
Use this terminal to connect a potential equalization conductor to a busbar in rooms where potential equalization is required.

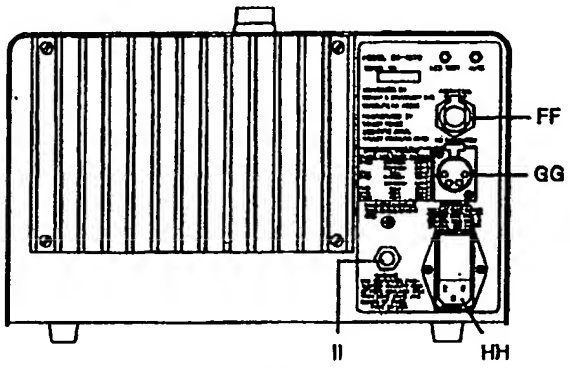


Figure 7. **Back Panel Connections** (Items FF through II)

Instructions for Use

Set Up

1. Place the CMC-III generator on a stand convenient to the surgeon. We recommend the use of the CODMAN Floorstand for MALIS CMC-II/III (catalog no. 80-1177).

NOTE: Make sure the power switch is in the OFF position.

2. Plug the power cord into the rear panel of the generator and then into an appropriate voltage grounded electrical outlet.

WARNING: Grounding reliability can be achieved only when connected to a receptacle marked "Hospital Only" or "Hospital Grade."

3. Look at the power receptacle and verify that the appropriate supply voltage setting is shown in the window. If you must change the setting, use a tool, such as a screwdriver to pry down the top edge of the panel (A in Figure 8). Using a fingernail or screwdriver, gently pull the two fuse holders out and completely remove them, then pry out the voltage selection drum (Figure 8a). Turn the drum and reinsert so the appropriate power setting will appear in the window. Reinsert the fuse holders so the arrows match the arrows on the inside of the panel. Snap the panel back into position.

WARNING: Always replace the system's fuse with the appropriate type and value fuse (see Technical Specifications).

If you must make a significant change to the supply voltage setting, such as from 110/120V to 220/240V operation, two internal fuses must be replaced. This should be done by a qualified person. Please refer to the Technical Specifications for instructions.

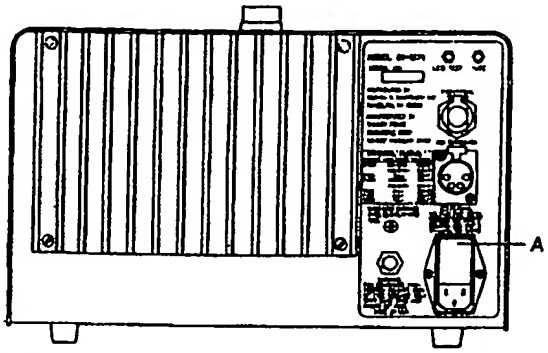


Figure 8.

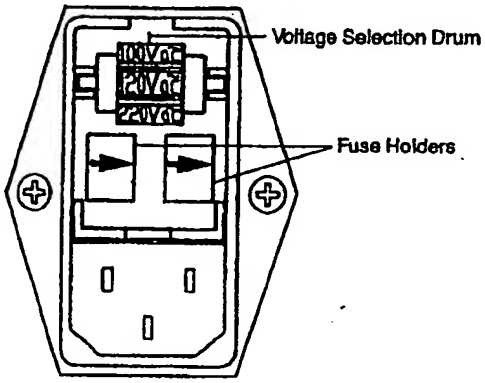


Figure 8A.

4. Insert the plug of the footpedal into the footpedal receptacle on the rear of the generator. Place the footpedal in an area accessible to the user.

NOTE: Be sure to test the integrity of the footpedal before each use. Replace if necessary.

NOTE: Do not immerse the footpedal in any liquids. Inspect the footpedal cord before use and replace the footpedal upon any evidence of deterioration.

5. If you're using the MALIS CMC-II Irrigation Module with the CMC-III System:

A. Follow the set up instructions provided with the MALIS irrigator, with the exception of installing the footpedal.

B. Connect one end of the CMC-III/Irrigator Connecting Cable into the footpedal receptacle on the rear of the irrigator. Connect the other end of the cable into the irrigation receptacle on the rear of the CMC-III generator. The cable allows you to control irrigation and cutting or coagulation simultaneously with the CMC-III footpedal or remote control.

C. Continue with the set up of the irrigator. Use only MALIS design tubing with the CMC-III. Refer to the instructions provided with the tubing set.

NOTE: To avoid unintentional irrigation, be sure the power on the irrigator is switched off whenever the CMC-III generator is switched off.

Preliminary Instructions

NOTE: Before turning on the generator, verify that the supply voltage selector on the power receptacle is set to the correct voltage for the electrical outlet.

1. Press the power switch to the ON position. The microcut and coagulation power setting windows will illuminate when the power comes on. When the generator is first turned on, they will default to power settings of 35 MALIS Units. You may press the watts display button on the front panel at any time to change to or from the watts mode. Whenever the watts mode is activated, the green watts LED will illuminate.

2. As soon as numerals are displayed in the power setting windows, the voice indicator will announce "thirty-five." Use the voice volume control to increase or decrease the volume as you wish. Adjust the tone volume by using the tone volume control located on the front panel. While you are using the tone volume or voice volume controls, the tone or voice settings will appear in the microcut power display window. Afterwards, the display window will again show the actual microcut power setting.

3. Place the remote control into a sterile transparent plastic bag, such as those used for operating room cameras. Place the remote in an accessible area of the sterile field. For best results, aim the remote as directly as possible toward the front panel of the generator. Make sure the infrared signal receiver window (Item DD in Figure 5) is not obscured.

4. Using Bipolar Cords

Using sterile technique as appropriate, place the forceps end of the sterile bipolar cord in an accessible area of the sterile field. Pass the cord and banana plug connectors out of the sterile field to the generator. Insert the banana plugs into the isolated bipolar output jacks. Be sure both plugs are securely inserted into the jacks. Attach the sterile bipolar forceps to the sterile end of the bipolar cord. Remove the plugs by grasping and pulling the molded strain reliever only; do not pull on the cord itself.

NOTE: Be sure to test the integrity of the bipolar cord before each use. Replace if necessary.

5. Using the Irrigation Tubing Set

Please refer to the product insert packaged with the tubing set for specific set up instructions.

NOTE: To avoid unintentional irrigation, be sure the power on the irrigator is switched off whenever the CMC-III generator is switched off.

6. Change the cutting and coagulation power settings to the desired amount by pressing the Cutting Power Control Switch and the Coagulation Power Control Switch on the front panel of the generator or on the remote control set. To return quickly to the original power setting of 35 MALIS units (9 watts), use th cut and coag reset buttons on the front of the generator.

Dr. Leonard Malis states the following:

"In terms of power settings, there are too many variables to recommend specific output power selections. Forceps tip size, vessel diameters, and tissue size all must be considered when choosing a power setting. As with all electrosurgical devices, proper care should be taken to prevent use of a setting which is in excess of that needed to cut or coagulate. Shrinking the neck of an intracranial aneurysm could require a setting of 20 or 25 (3 to 5 watts). Coring of an intracranial tumor may be accomplished at power between 35 and 45 (9 to 14 watts). Depending on the size of the forceps, skin flap hemostasis may be achieved at settings between 30 and 50 (7 to 17 watts). Larger vessels in the muscles of the abdomen or back may require higher settings. Experience suggests that each surgeon determine the output setting which provides optimum results by beginning with th lower settings of the MALIS CMC-III and adjusting upward as required."

NOTE: Depress the Power Control Switches firmly to avoid partial or transient operation and to achieve correct switch function.

NOTE: Never adjust the power settings while using the Cut or Coag controls on either the footpedal or the remote control.

Operating Instructions—Coagulation Mode

When either the right (Coag) pedal of the footpedal or the right (Coag) button of the remote is depressed, the following will occur.

1. The voice indicator confirms the mode by NOT ANNOUNCING THE WORD "CUTTING."

2. The voice indicator and the coagulation power display will respectively announce and display the power setting simultaneously.

3. Immediately following announcement of the power setting, you will hear a low frequency major chord tone. The blue coagulation light will illuminate to verify the use of the coagulation mode. Simultaneously, the green Power Output LED illuminates, indicating that power is being delivered via the isolated bipolar output jacks to the forceps tips.

4. Release the Coag button on the remote control (or the Coag pedal on the footpedal) to cancel the sequence and stop delivery of power to the forceps. To begin coagulation again, depress the button or footpedal once more.

WARNING: When using the remote control to cut or coagulate, pause for at least two seconds before your next selection to allow the power output cycle to complete itself.

NOTE: Depress the pedal or button firmly to avoid partial or transient operation, to achieve correct switch function.

NOTE: Never adjust the power settings while using the Cut or Coag controls on either the footpedal or the remote control.

Coagulation in Mute Mode

If desired, you may eliminate the voice indicator by depressing the Mute Button on the back panel of the generator. The green Mute LED will then light up. Thereafter, the voice indicator WILL NOT ANNOUNCE the power setting. When you depress either the Coag pedal on the footpedal or the Coag button on the remote, coagulation power will **immediately** be delivered, accompanied only by a low frequency major chord tone and the illumination of the blue coagulation light. The green Power Output LED will simultaneously light up.

Even in the Mute Mode, the voice indicator will continue to announce the power setting whenever that setting is changed and will announce any of the five problems detected by the self-diagnostic function.

Operating Instructions—Cutting Mode

When either the left (Cut) pedal of the footpedal or the left (Cut) button of the remote are depressed, the following will occur.

1. The voice indicator confirms the mode by announcing either "Microcut" or "Cutting."

2. The voice indicator and the micro or high cutting power display will respectively announce and display the power setting simultaneously.

3. Immediately following announcement of the power setting, you will hear a high frequency minor chord tone. Either the yellow microcutting or the yellow high power cutting LED, as appropriate, will light up to verify the cutting mode. Simultaneously, the green Power Output LED illuminates, indicating that power is being delivered via the isolated bipolar output jacks to the forceps tips.

4. Release the Cut button on the remote control (or the Cut pedal on the footpedal) to cancel the sequence and stop delivery of power to the forceps. To begin cutting again, depress the button or footpedal once more.

WARNING: When using the remote control to cut or coagulate, pause for at least two seconds before your next selection to allow the power output cycle to complete itself.

NOTE: Depress the pedal or button firmly to avoid partial or transient operation, to achieve correct switch function.

NOTE: Never adjust the power settings while using the Cut or Coag controls on either the footpedal or the remote control set.

Cutting in Mute Mode

If desired, you may eliminate the voice indicator by depressing the Mute Mode Button on the front panel of the generator. The green Mute Mode LED will then light up. Thereafter, the voice indicator WILL NOT ANNOUNCE either the operating mode ("Microcut" or "Cutting") or the power setting. When you depress either the Cut pedal on the footpedal or the Cut button on the remote, cutting power will **immediately** be delivered, accompanied by a high frequency minor chord tone and the illumination of the yellow microcutting or high power cutting LED. The green Power Output LED will simultaneously light up.

Even in the Mute Mode, the voice indicator will continue to announce the power setting whenever that setting is changed and will announce any of the five problems detected by the self-diagnostic function.

Troubleshooting Guide

Symptoms	Probable Cause	Correction
1. Unit does not operate (Power-on indicator light)	a. Blown fuse b. Loose wire at power cord plug c. No power at wall outlet	a. Replace fuse b. Check plug for wiring c. Check electrical service
2. Low power output	a. Low line voltage	a. Adjust to 120, 220, or 240 volts nominal, as appropriate
	b. Incorrect test load	b. Use 50 ohm non-inductive load for coag and microcut; 400 ohm for regular cut
	c. Internal calibration change	c. Return for service and recalibration
3. Erratic power output	a. Loose or dirty connections between forceps cord and jacks b. Intermittent break in forceps cord	a. Gently clean plug surfaces with abrasive cloth b. Replace forceps cord
4. No power output	a. Broken wire in forceps cord	a. Replace forceps cord
5. Excessive leakage current	a. Shorted output transformer	a. Check for shorting to core case. Return for service and recalibration
6. Excessive power output	a. Internal calibration change	a. Return for service and recalibration
7. Voice indicator announces "Internal fuse." Power Setting Display flashes "00"	a. Blown internal fuse	a. Replace internal fuse
8. Voice indicator announces "Memory error"	a. Operating malfunction	a. Return for service
9. Voice indicator announces "Error"	a. Two front panel setting controls pressed simultaneously	a. Use care when pressing controls
10. Voice indicator announces "Footpedal error"	a. Two footpedals pressed simultaneously	a. Use care when depressing footpedal
11. Voice indicator announces "Internal power error"	a. Operating malfunction	a. Return for service

Technical Specifications

Power Requirements
100 ± 10% VAC with 100 selected on the supply voltage selector
120 ± 10% VAC with 120 selected on the supply voltage selector
220 ± 10% VAC with 220 selected on the supply voltage selector
240 ± 10% VAC with 240 selected on the supply voltage selector
50/60Hz 400 Watts

Fuses

External For 100 or 120 VAC operation:
Two 4.0 Amp Type T (MDL) (125 VAC)
For 220 or 240 VAC operation:
Two 2.5 Amp Type T (MDL) (250 VAC)

Internal
Mother Board: Two (F600, F601) 3.0 Amp Type F (AGC) 250 VAC
One (F602) 0.5 Amp Type F (AGC) 250 VAC

High Voltage Power Supply Board:
F400: 4.0 Amp Type T (MDL) 250 VAC for 100/120V operation
2.5 Amp Type T (MDL) 250 VAC for 220/240V operation
F401: 2.0 Amp Type F (AGC) 250 VAC
F402: 1.0 Amp Type T (MDL) 250 VAC for 100/120V operation
0.6 Amp Type T (MDL) 250 VAC for 220/240V operation

AC Leakage Current
Less than 10 μA with power ON or OFF, polarity normal or reversed, with ground open or connected.

Output Waveforms
Coagulate: Damped Aperiodic, centered at 1MHz
Cut: Sinusoidal, 1MHz

Output Power Range
Coagulate (20 settings) .72–50 watts into 50 ohm non-inductive resistor load
Micro Cut (10 settings) .72–16.8 watts into 50 ohm non-inductive resistor load
Cutting (10 settings) 20–200 watts into 400 ohm non-inductive resistor load

Output Setting Indications
Visual: Three-digit indicators, except micro cut, which is two-digit
Aural: Voice annunciator (synthesizer)

Power Controls
AC: ON/OFF Switch
RF Output: Panel mounted three-position rocker types

Panel Connectors
Bipolar: Two high voltage jacks

Cooling
Convection; no fan

Weight
21 lb. (10.4 kg)

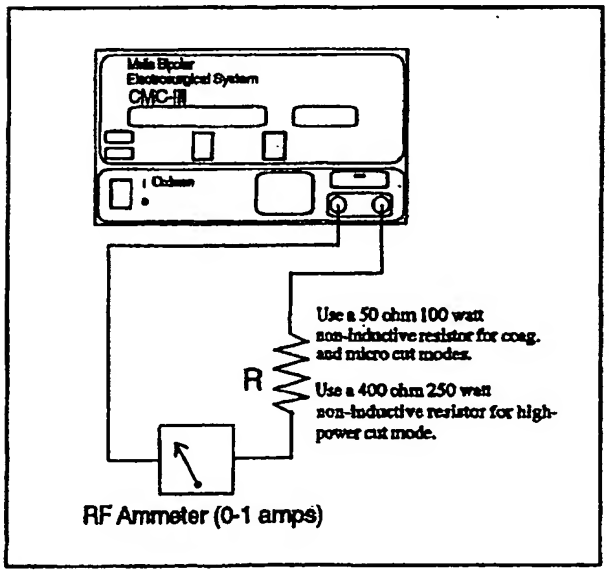
Dimensions
8½H x 12¾W x 17D inches
21.6H x 32.4W x 43.2D centimeters

Minimum Operating Temperature
50°F (10°C)

Remote Control Power Source
Two 1.5v AAA alkaline batteries

Operational Performance

The MALIS Bipolar Electrosurgical System CMC-III may be tested for operational performance using 50 ohm and 400 ohm non-inductive test loads and RF ammeter or equivalent electrosurgical analyzer. A test set up is shown in the accompanying figure with typical values for each power setting. It should be noted that these are typical values and that output power may vary depending on line voltage, load resistor tolerances, and meter accuracy.



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Typical Output vs P wer Setting

(For referenc only)			Coag. Output Into 50 ohms	
Power Setting Mode (Mails Units)		**(Watts)**	**Output Current (RF amp)**	**Output Power (Watts)**
8	-	0.7	0.12	0.72
10	-	1.0	.15	1.1
15	-	1.6	.18	1.6
20	-	3.	.24	2.9
25	-	5.	.32	5.1
30	-	7.	.38	7.2
35	-	9.	.43	9.3
40	-	11.	.48	11.5
45	-	14.	.53	14.1
50	-	17.	.58	16.8
60	-	19.	.62	19.2
70	-	22.	.66	21.3
80	-	24.	.69	23.3
90	-	25.	0.71	25:2
100	-	29.	0.76	28.9
110	-	32.	0.80	32.0
120	-	35.	0.84	35.3
130	-	40.	0.89	39.6
140	-	45.	0.95	45.1
150	-	50.	1.00	50.0

			Cut Output		
Power Setting Mode (Mails Units)		**(Watts)**	**Output Current (RF amp)**	**Output Power (Watts)**	
	8	- 0.7	.12	0.72	
	10	- 1.0	.15	1.1	
	15	- 1.6	.18	1.6	
	20	- 3	.24	2.9	
Micro-	25	- 5	.32	5.1	Into
Cut	30	- 7	.38	7.2	50 Ohms
	35	- 9	.43	9.3	
	40	- 11	.48	11.5	
	45	- 14	.53	14.1	
	50	- 17	.58	16.8	
	60	- 20	.22	20.0	
	70	- 40	.32	40.0	
	80	- 60	.39	60.0	
	90	- 80	.45	80.0	
Cut	100	- 100	.50	100.00	Into
	110	- 120	.55	120.00	400 Ohms
	120	- 140	.59	140.00	
	130	- 160	.63	160.00	
	140	- 180	.67	180.00	
	150	- 200	.71	200.00	

R placing Internal Fuses

Significant changes in the supply voltage setting, such as from 110/120V to 220/240V, will require a change in two internal fuses. Fuses F400 and F402 are located on the power supply board. Figure 9 shows the location of the power supply board in the CMC-III chassis.

1. Disconnect the generator from the power supply.

2. Remove the six Phillips head screws and washers holding the cover in place. Remove the cover.

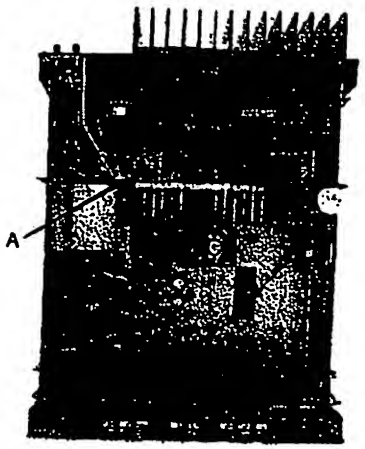

Figure 9.

3. Remove the Phillips head screw (Item A in Figure 9) that holds the power supply board to the metal bracket.

4. Firmly pull the power supply board upward until you can disengage it from the card holders on either side. Do not attempt to pull the board completely out of the chassis; it's still connected via the supply voltage wiring.

5. Remove fuses F400 and F402 (see Figure 10), replace them with the appropriate type and value fuses (see Technical Specifications).

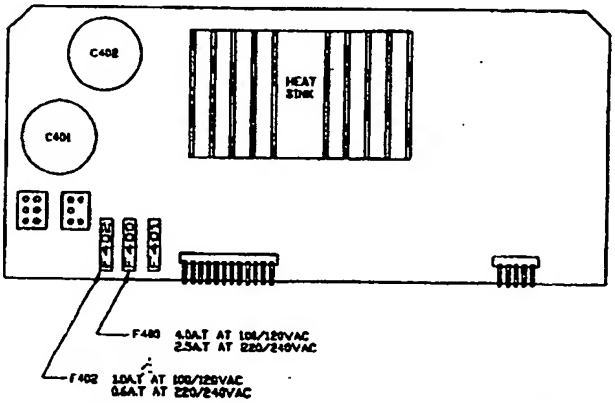

Figure 10. **Changing Internal Fuses on Power Supply Board**

6. Slide the board back into the card holders, making sure the pins on the bottom of the board align with their connectors. Push the board down firmly until the pins seat properly in the connectors.

7. Replace the screw holding the board to the bracket. Replace the cover and the six screws and washers.

WARNING: The supply power setting drum, located on the power receptacle at the rear of the generator, must also be set to the correct voltage for the electrical outlet before the generator is turned on.

Maintenance

Bipolar Forceps

Proper care and maintenance of the bipolar forceps is essential to efficient cutting and coagulation. Dr. Malis states th following:

"While some sticking and charring of the bipolar cutting and coagulation forceps is unavoidable, the elimination of the initial overvoltage spike in the MALIS CMC-III waveform greatly reduces the incidence of sticking and charring. Coupled with additional waveform modifications, the MALIS CMC-III can be used with less irrigation (or no irrigation at all, if required) while reducing sticking and charring to levels lower than heavily-irrigated spark gap and solid state generators. Because the generator is effective at lower settings, pitting of the forceps tips which normally occurs is greatly reduced."

Remove coagulum deposits as often as necessary to keep working surfaces clean. This will ensure the flow of current between the forceps tips. We recommend Johnson & Johnson Medical's Electro-Surgical Tip Cleaner (J&J Medical catalog no. 3415). If tips become pitted or misaligned, return the forceps to Codman for repair or replacement.

Bipolar Cord

Low or erratic performance may be due to poor contact between the bipolar forceps cord plugs and the isolated bipolar output jacks on the generator. Badly oxidized surfaces will impede current flow. Use an abrasive cloth to gently clean plug surfaces to keep them clean and bright. Inspect the bipolar cord before each use and replace it upon evidence of any deterioration.

NOTE: Pulling plugs from the jacks of the MALIS CMC-III by grasping the cord could damage the cords and cause intermittent operation. Disconnect the plugs by holding the plug with one hand and the generator with the other.

Fo tpedal

Storing the footpedal with the pneumatic tubing tightly wrapped around it may damage the tubing. Leave sufficient slack to prevent stress on the tubing. Inspect the tubing before each use and replace the footpedal upon evidence of any deterioration.

Power Cord

Never use extension cords, three-prong to two-prong power plug adaptors or extra length power cords with the MALIS CMC-III. Before each use, visually inspect the power cord and plug for frayed or broken insulation. If necessary, replace the power cord with the same type, length, gauge, and insulation.

Remote Control

The remote control uses two 1.5v AAA alkaline batteries. To open the battery compartment, press down on the lower portion of the remote's rear cover and slide it down. Remove the old batteries. Insert new batteries as illustrated within the compartment. Slide cover back on until it snaps into position.

Routine Cleaning

The MALIS CMC-III generator cabinet may be cleaned with a damp cloth or sponge. Alcohol or mild cleaning solutions may be used to remove stains or adhesives that may stick to the cabinet. DO NOT immerse the MALIS CMC-III generator or remote control in any liquid. Subjecting the generator to excessive moisture may damage the electronic components and violate the warranty.

The CMC-III footpedal may be washed with any normally used hospital cleaning liquids. Take care to ensure that no liquid enters the white plastic footpedal connector.

Sterilization

Never sterilize the MALIS CMC-III generator, footpedal, remote control, or connecting cable. Place the remote into a sterile plastic bag similar to those supplied for operating room cameras.

The Integrated Irrigation Tubing and Cord Set is sold sterile and is a single-use device. Do not resterilize.

Service and Repair

For service or repairs to the MALIS CMC-III generator and footpedal, contact your local Codman sales representative directly or through Codman Customer Service, 1-800-225-0460.

The sales representative will coordinate the return to:

Codman Repair Service
c/o Codman & Shurtleff, Inc.
4969 Wakefield Street
Philadelphia, PA 19144

Be sure to include with the unit a repair purchase order number, the serial number of the generator, and a written description of the problem.

The MALIS CMC-III Remote Control is not repairable. Replacements are available from:

Codman & Shurtleff, Inc.
Pacella Park Drive
Randolph, MA 02368

Accessories

Description	Catalog No.
Bipolar Cord	30-1536
MALIS Bayonet Bipolar Cutting Forceps, Right, 8" (20.3cm)	80-1143
MALIS Bayonet Bipolar Cutting Forceps, Left, 8" (20.3cm)	80-1144
MALIS Bayonet Bipolar Cutting Forceps, Straight, 5½" (14.0cm)	80-1145
MALIS Bipolar Cutting Forceps Set (includes left and right bayonet)	80-1146
MALIS Integrated Irrigation Tubing and Cord Set	80-1163
MALIS Irrigation Module	80-1164
MALIS CMC-III Air Footpedal (includes footpedal, cord and plug)	80-1173
MALIS CMC-III/Irrigator Connecting Cable	80-1174
MALIS CMC-III Remote Control Set	80-1175
CODMAN Floorstand for MALIS CMC-II/III	80-1177

A variety of standard non-cutting bipolar forceps is also available.

Warranty

The MALIS Bipolar Electrosurgical System CMC-III is warranted for one full year from date of purchase, except the Remote Control Set which is warranted for six months. The MALIS CMC-III is warranted to be free from defects in both materials and workmanship. Disassembly, alteration, or repair performed by any person not authorized by Codman & Shurtleff, Inc., will result in immediate loss of warranty. THE ABOVE WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Suitability for use of the device for any surgical procedure shall be determined by the user. Codman shall not be liable for incidental or consequential damages of any kind.

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Distributed by:

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